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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,234	02/28/2002	Sham Chopra	4769-102 US	1779

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EXAMINER	
PULLIAM, AMY E	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,234	CHOPRA, SHAM	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication app ars on th cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,21-30,36-45,51-62 and 64* is/are pending in the application.

4a) Of the above claim(s) *12-20,31-35,46-50 and 63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,21-30,36-45,51-62 and 64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Petition to Make Special and the Status request, received by the Office February 28, 2002 and June 9, 2003, respectively.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 21-33, 36-48, 51-62, and 64, drawn to a chemical delivery device and a method of delivering an active agent via said device, classified in class 424, subclass 464.

II. Claims 15-20, 34, 35, 49, 50, and 63, drawn to a process for the preparation of a chemical delivery device, classified in class 264, subclass 109.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the chemical delivery device described by Applicant can be read as a tablet, and it is well known in the pharmaceutical art that there are many ways to formulate tablets. One such method is direct compression, which is distinguishable from the instant method claimed by Applicant.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I above is selected, then please elect from the following species:

A. Type of active agent: a pharmaceutical agent for human use, an insecticide, a fungicide, a biocide, and a disinfectant.

If group II is selected, then please elect from the following species:

A. Type of granulation: Wet granulation and dry granulation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant's Election

Applicant's election without traverse of group I, claims 1-14, 21-33, 36-48, 51-62, and 64, in the telephone election, is acknowledged. Claims 15-20, 34, 35, 49, 50, and 63 are withdrawn from consideration.

Additionally, the election required by the examiner concerning the particular shape of the device has been withdrawn. The election regarding the particular active agent is maintained, and Applicant's election of a pharmaceutical agent for human use is acknowledged. In response to this election, claims 12-14, 31-33, and 46-68 are also withdrawn from consideration.

Claim Objections

Claims 23, 24, 38, and 39 are objected to because of the following informalities: A claim should be able to stand alone, without reference to the specification or drawing. Each of the listed claims refers to a figure within the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "polymer coating" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 21-30, 36-45, 51-62, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,922,342 to Shah *et al.* in view of US Patent Application Publication US 2001/0038853 to Kendrup *et al.*

Shah *et al.* disclose a controlled release composition which provides constant drug release (column 3, lines 18-24). The dosage form comprises a compressed core containing a drug and having two parallel planar surfaces and a seal coating surrounding the core except on said planar surfaces (column 3, lines 25-30). Shah *et al.* further teach that the compressed core may be of various shapes, including circular, triangular, elliptical, hexagonal, and others, as long as the core has two parallel planar surfaces, usually easily identified as the top and bottom surfaces (column 3, lines 35-40). Shah *et al.* also disclose that the compressed core can contain inert ingredients that are conventional in tablet making (c olumn 4, lines 26-44). Shah *et al.* also teach that the compressed core is coated with an impermeable seal coating, such as polyvinyl acetate, ethyl cellulose, cellulose ethers, or others (column 5, lines 23-29).

Shah *et al.* do not teach that the coating layer comprise pore formers.

Kendrup *et al.* disclose a method for producing a controlled release pharmaceutical preparation with a particle containing coating, the coating being derived from an aqueous dispersion of a film-forming water insoluble polymer and a water soluble pore forming agent. Kendrup *et al.* teach a variety of pore formers (see page 2, paragraphs 19-22), including carbohydrates. Additionally, Kendrup *et al.* teach several possible water insoluble polymers to be used as the coating material, including cellulose esters, acrylic polymers, polyvinyl acetates, and others (see page 2, paragraphs 23-25). Kendrup *et al.* also discuss that the inclusion of water soluble pore formers is known in the art, to make a polymer coating micro-porous and to increase the release rate of the drug through the coating (page 1, paragraphs 2-4).

One skilled in the art would know that in the field of pharmaceutical dosage forms, coatings can be interchanged, depending upon what the intended result is. In this instance, Shah

et al. teach an impermeable coating. However, if an increase in the release rate were desired, due to the use of moderately soluble drugs or preparations with small surface areas, one skilled in the art would know to include pore formers in the coating. Pore formers have been used in the pharmaceutical art for years, and are known to increase the rate of release of the active within the core of a pharmaceutical dosage form. The expected result would be a formulation with the benefits disclosed by Shah *et al.*, however, with an increased rate of release. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
September 29, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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